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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,774	03/24/2004	Juergen Dannenmaier	N0060US02	2773

24994 7590 09/15/2006

GAMBRO, INC
PATENT DEPARTMENT
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EXAMINER

MENON, KRISHNAN S

ART UNIT PAPER NUMBER

1723

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/708,774

Applicant(s)

DANNENMAIER ET AL.

Examiner

Krishnan S. Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 13, 17, 18, 25-35, 37 and 40-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-12, 14-16, 19-24, 36, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-43 are pending

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-30, 36-43, drawn to filter device, classified in class 210, subclass 321.78.
- II. Claims 31-35, drawn to method of making filter device, classified in class 156, subclass 303.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by materially different process steps, such as welding, melt-sealing or adhesives.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

Device structure: represented by figure 2 and 5; represented by figure 2a and 5a; and the 3-compartment structure.

Shell portion having (1) different color (2) different refractive index

Method of joining shell (1) ultrasound weld, (2) laser weld, (3) adhesive.

The species are independent or distinct because the result in different structures or process steps.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

During a telephone conversation with Mr. John Merkling on 9/12/06 a provisional election was made without traverse to prosecute the invention of group I, claims 1-6, 10-12, 14-16, 19-24, 36, 38 and 39; with species represented by figures 2 and 5, shell having different refractive index and adhesive as the bonding method. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-9, 13, 17, 18, 25-35, 37 and 40-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that since the product claims are elected, process claims would be allowable if product claims are found allowable and if the process claims contain all the limitations or are dependent on the product claims.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in EPO on 4/11/03. It is noted, however, that applicant has not filed a certified copy of the EPO application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,4,5,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al (US 5,882,516).

Claims 1,4,5: Gross teaches a hollow fiber membrane cartridge (figure 1) having two internal compartments (20 and 22) separated by a common wall (18), each compartment having hollow fibers (42), with inlets and outlets (34,36,38,40 and 44), and one of the longitudinal shell portion forming the smaller of the two compartments has less than half the perimeter. Housing is tubular, and the perimeter is the circumference.

Claim 16 and 19-21: the functional arrangement of the filter in figure 1 and 2 are the smaller side is for ultrafiltration and the larger side is for dialysis – see column 2 lines 33-44. The exterior surface of the hollow fibers of the smaller chamber is in fluid communication with the interior side of the hollow fibers of the larger chamber.

Claim 22-24: the cartridge is assembled as claimed – see figures 1 and 2.

2. Claims 6,10-12 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gross.

Claim 6 recites longitudinal seams in the shell, and claims 10-12 recite the assembly process of the shell. However, these limitations are purely for the process of making the device, which do not other wise make any structural difference to the device. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-

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process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross

Claims 2 and 3 recite the perimeter of the shell portions as less than a third or a quarter of the housing, which is not specifically taught by the reference. However, the size of the shell would depend on the size of the filter to be accommodated, which would depend on the quantity of fluid to be processed, and one of ordinary skill in the art could optimize this size for the intended purpose. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

4. Claims 14,15,36,38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross as applied to claim 1 above, and further in view of Pope et al (US 2003/0102264).

Claims differ from the teaching of Gross in the recitation of the longitudinal shell portions having material with different refractive index, and particularly, polycarbonate and polypropylene. Applicant's stated purpose for the different refractive index in the materials is for monitoring the weld quality between the two shell portions, which is only a manufacturing step, and does not appear to otherwise contribute to the structure of the product. Since no other criticality appears to be disclosed for the choice of the materials, and because applicant elected 'adhesive' as the means for joining the shell portions, the choice of the refractive index of the material, or the choice of polypropylene and polycarbonate, are not patentable limitations. Pope teaches that both polypropylene and polycarbonate can be used for making the dialyzer shell, with polycarbonate being better for visibility, whereas polypropylene is cheaper (see paragraph 20). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Pope in the teaching of Gross to have either, or a combination, of polypropylene and polycarbonate. One would use polycarbonate over polypropylene for the parts that require transparency, such as the part of the shell where blood flows through the membrane, so that any blood leak is clearly visible, and polypropylene for others to reduce the cost.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Krishnan S Menon
Examiner
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